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EXAMINER
PADGETT, MARIANNE L

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Please find below and/or attached an Office communication concerning this application or proceeding.

AS6

Office Action Summary	Application No. 09/849,065	Applicant(s) Ward D. Halverson
	Examiner M.L. Padgett	Group Art Unit 1762

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on 8/30/01 + 9/7/01 + 10/26/01.

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-48 is/are pending in the application.

Of the above claim(s) 40-48 and 30 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-29 and 31-39 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-39, drawn to an ECR plasma method of treating tubular (lumen) substrates, classified in class 427, subclass 575.

II. Claims 40-48, drawn to an ECR and/or microwave plasma apparatus, classified in class 118, subclass 723 MR.

2. The inventions are distinct, each from the other because:

Inventions group I and group II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus may be used to treat substrates other than lumens or tubular objects, as the substrates are not part of the apparatus, and solid rods, or continuous rope like substrates, etc., would have had shapes capable of being treated in the claimed apparatus.

3. Claims 1-21, (24), 26, (27-28), 29-39 are generic to a plurality of disclosed patentably distinct species comprising:

(i) inorganic;

(ii) organic - (a) bioactive

- (b) hydrocarbon and derivatives.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Thomas Engellenner on 11/13/02 a provisional election was made with traverse to prosecute the invention of group I method, coating spices of (ii) organic (a) bioactive compounds, claims 1-26, (27-28) and 29-39. Affirmation of this election must be made by applicant in replying to this Office action. Claims 40-48 (and claim 27-28 if hydrocarbons are used for coating) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Claims 4-18, 20-29 and 33-39 are objected to or rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, it is ambiguous whether the phrase "irradiating a gas...flowing through said region..." is intended to mean that the irradiation is done while the gas is flowing through the region and while in the region; or if it can also include pretreatment of the gas, i.e. remote irradiation, when the irradiated gas is flowed through the region. From the specification, as illustrated by the figures (plasma in ECR zone), it appears that only *in situ* plasmas are intended, but clarification in the record to remove the ambiguity is needed.

In claims 8 and 9, where are there relationships satisfied? The amplitude of a magnetic field is not generally constant throughout a reactor, but varies over space along different magnetic field lines as illustrated by Fig. 3 in Yamazaki (PN. 4689,923). The relevance of these formula or relationships, without knowing the configurational relationships with respect to the claimed steps is unclear. Also, concerning claim 9, a ratio is generally a dimensionless quantity, i.e. the units of the compared value cancel out, but f_c in Hertz and B in Gauss, give f_c/B = Hz/G, which is not unitless, so claims 9 will be considered as a formulistic relationship, noting that $f_c/B = e/2\pi m$ as given in claim 8 and Eq. (i) on p. 2 of the specification. If one uses the electron charge to mass ratio of $e/m_o = 1.75896 \times 10^7$emu, $f_c/B = 0.27997 \times 10^7$ or approximately 2.8×10^6, so claims 8 and 9 appear to be expressing the same relationship, where the given units Hz and Gauss are employed (and apparently emu, although the examiner does not known the

relationship between Hz, G and emu, from the formula presumably H_z/Gauss = emu (electromagnetic unit).

Claim 17 requires "uniform speed" to provide "a substantially uniform treatment", while claim 18 which depends therefrom claims "non-uniform speed" to create "graded treatment", thus contradicting claim 17. Is the dependence of these claims correct or should both depend from claim 16? Or should there be clarifying language to distinguish "selected portions" of claims 16 and 17? Claim 18 is further vague and indefinite because the antecedence of "selected portions" is unclear as it does not use an article showing antecedent basis, but is not differentiated from the identical term in claim 17. Note claim 1 introduces "at least a portion", claim 16 "different portions" and claims 17+18, both introduce "selected portions", but no clear relationship between any of these portions has been claimed, or indicated through article usage.

Claim 20 is objected to (not rejected), as "the step of coating" is newly introduced so lacks proper antecedent basis.

In claim 23, "said anti-coagulant material" is one of 4 options, but while it is further defined in this claim, it is never positively chosen as the option used, hence it is implied but not necessitated, so is vague and indefinite or uncertain.

In claim 33 "a selected partial pressure" (emphasis added) implies that there is some other gas present besides "said gas" which has been claimed, so the total pressure may be completely different than the partial, and any part of a mixture may consider to have been selected. However, since only one "gas" has been positively introduced, the intent of "partial" is unclear.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-2, 4-5, 8-12, 16-17, 29 & 32-36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wilhelm.

The patent to Wilhelm teaches use of a microwave plasma to coat the internal surfaces of pipes (i.e., the lumen thereof), via CVD reactions at subatmospheric pressures. Microwaves are propagated along the length of the tube (pipe), while a magnetic field is generated in a localized area so that electron cyclotron resonance (ECR) occurs, causing plasma which results in deposition. The magnetic field is moved along the length of the pipe to produce a homogeneous plasma coating (considered equivalent to uniform), although other "desired profiles" may also be produced. See the abstract, Fig. 1 and Summary. Note that the process is taught to be applicable to all

coatings that may be produced by conventional thermal or plasma CVD processes, giving examples of specific (inorganic) ceramic coatings. Exemplary uses include internal coatings in waveguides to prevent breakdown field strength, and coating insides of pipes for corrosion protection (col. 2, line 3-15). This later use is considered to read on "sealing". Also, whether or not its used for that purpose, the plasma conditions will have the effect of inherently sterilizing treated surfaces, as the produced heat and radiation will kill germs, etc.

While no generalized parameter ranges are given, the example on col. 3, lines 10-21, uses the frequency of 2.45 GHz (2.45×10^9 Hz), local magnetic field strength of 870 Gauss and gas density (pressure) of a few microbars (1 bar = 10^5 Pa; 1 μbar = 0.1 Pa), so $f_c/B = 2.45 \times 10^9$ Hz/870G ≈ 2.8×10^6 Hz/G, thus reading on claimed relationships (as would have been expected when ECR is produced) and parameters.

9. Claims 6-7, 14-15, 18 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilhelm.

While the single example in Wilhelm does not use values in these claimed ranges, it would have been obvious to optimize process parameters for particular tubular substrates being treated, especially as Wilhelm teaches (col. 2, lines 57-65) that pressure, magnetic field strength, microwave frequency and power all need to be selected so ECR occurs. For pressure also note that a few μbar (1 μbar = 0.1 Pa) is within an order of magnitude of the specifically claimed approximately 5 Pa, so well within the realm of optimization and routine experimentation.

While no specific tube or pipe diameters are discussed, there is no limitation placed on the inner diameters that may be treated, and those claimed are typical of many conventional fluid handling pipes, which are suggested for treatment in Wilhelm. The teachings of desired coating profiles, suggest those that change which would include what a "graded treatment" would produce, so such effects would have been obvious to one ordinary skill.

10. Claims 19-22, 24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilhelm as applied to claims 1-2, 4-18, 29 and 32-39 above, and further in view of Williams et al (4,927,676)

Claims 19-23 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilhelm as applied to claims 1-2, 4-18, 29 and 32-39 above, and further in view of Makker et al.

Claims 19-24 and 27-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Wilelm as applied to claims 1-2, 4-18, 29 and 32-39 above, and further in view of Narayanan (5,486,357).

While Wilhelm teaches that any coatings that may conventionally employ plasma deposition may be used for ECR deposition inside tubular or pipe shaped substrates, he hoes not specifically suggest plasma treating non-conducting organic substrates to enable bioactive coatings such as heparin, proteins or enzymes, or materials with anti-inflammatory or growth properties, nor any specific gases, such as Ar, O_2, N_2, CH_4, etc. Any of the secondary references { Williams et al ((676) see abstract; col. 1, lines 29-43; Summary; col. 3, line 43^+; col. 4, lines $17\text{-}60^+$; col. 6, lines 24-35 and Ex. II and III on

col. 7); Makker et al (abstract; col.2, lines 47-65; col. 3, lines 1-25 and 66 – col. 4, line 2; col. 6, lines 4-34 and esp. line 66- col. 7 line 30 and line 55- col. 8, line 9, heparin on line 3 and examples B, D, E, F and G on cols. 10-11); and Narayanan ((357), abstract; col. 1, line 14-29; col. 3, lines 17-49; col. 4, lines 9-56^{+}; col. 5, lines 10-23^{+} and 65 (heparin on line 66) – col. 6, line 10, with streptokinase and uroknase on line 1 which are enzymes or polypeptides, i.e. proteins; and Examples) } teach plasma treatment of polymeric tubing to deposit bioactive materials as claimed, where gases inclusive of Ar, O_2, N_2, etc., are disclosed. It would have been obvious to use the plasma procedures of Wilhelm to treat the tube interiors of Williams et al (676) or Makker et al or Narayanan (357), as the primary reference suggest it generically, and all the secondary references employ conventional plasmas, which Wilhelm, suggest replacing with his ECR plasma. In Williams et al (676), note the col. 4 teaching suggesting conventional plasma generators, including use of microwaves are useful, further supporting the stated obviousness. Note cells contain protein and enzymes. In Makker et al, note (col. 6, lines 20-27) times consistent with those claimed, along with teaching of routine experimentation to optimize, thus further supporting above contentions and enhancing lubricity is synonymous with reducing friction. In all the secondary references there are teaching on inner tube diameters, consistent with those claimed, again further supporting above stated obviousness.

11. Claims 3, 19-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilhelm as applied to claims 1-2, 4-18, 29 and 32-39 above, and further in view of Subramanian and Kieser et al.

As well as the above stated differences, Wilhelm does not teach the treatment of the outsides of tubes as well as or alternatively to the insides. Kieser et al (abstract; figures; col. 1, lines 9-30+; col. 2, lines 42-58; col.3, lines 45-62; col. 4, line 61-col.5, lines 20 and 58-68^{+}) teach that ECR microwave, employing the frequency and magnetic filed strength formula claimed by applicant, are also applicable to the exterior of long continuous substrates, including 3-dimensional shapes, hence demonstrating the equivalence of use of Wilhelm's type of plasma on exterior surfaces as well as interior.

Subramanian is similar to the secondary references applied above in section 9, teaching plasma treating polymeric substrates inorder to coat with bioactive materials, where the variety of possible materials includes heparin, or polypeptide sequences (i.e. protein material), antibiotics, antimicrobials, growth factors, etc. The types of substrates include catheters, vascular stents, and various elongated tubular members where the functions and uses clearly indicate need for taught coating in interior and/or exteriors. It would have been obvious to employ the process of Wilhelm et al to provide the required plasma treatment for the same reasons as discussed above in section 9. Further, as Subramanian shows that such substrates are also desirably treated on their exteriors, and illustrates porous tubular substrates as in Fig 5, analogous plasma treatment is suggested for the exteriors, where Kieser et al demonstrates the equivalent procedure applied to exterior as taught by Wilhelm for interiors, hence it would have been obvious to one of ordinary skill in the art that either interior or exterior of tubes would have been effectually and desirably treat by ECR plasmas as taught by Wilhelm and Kieser et al.

12. Other art if interest include Williams et al (4,613,517) and Narayanan et al (5,591,140) with further bioactive coating with plasma treatments.

13. Any inquiry concerning this communication should be directed to M L. Padgett at telephone number 703-308-2336 on M-F from about 8:30 am – 4:30 pm; FAX# (703) 872-3910 (regular); and 305-6078 (informal).

M. L. Padgett/mn 02/10/03
February 11, 2003

MARIANNE PADGETT
PRIMARY EXAMINER